



TANBead® Nucleic Acid Extraction Kit

HPV DNA Auto Plate

(For use with the SLA-16 / 32 / E13200 series)

RUO

61HA46

(For Research Use Only) V1

1. Intended Use

This product is designed for isolating nucleic acid from various samples, which can be performed by using TANBead® Nucleic Acid Extractor and is intended for research use only.

2. Purpose

The TANBead® Nucleic Acid Extraction Kit (61HA46) is designed to perform the HPV nucleic acids extraction. By using with TANBead® Nucleic Acid Extraction Systems, the one-step-to-extraction can be performed automatically. The cervical swab or liquid based cytology samples are processed through a series of automatic extraction steps and the high-quality nucleic acids can be applied directly to the further applications. The nucleic acids extraction performance of the HPV samples is examined.

3. The basic principle

The silicon dioxide layer coated on the magnetic beads can adsorb the negatively charged molecules to purify nucleic acids from samples.

4. Specification

Starting Materials	300 µL cervical swab or liquid based cytology samples
Elution Volume	50~80 µL

5. Component Supplied with the Kit

Auto Plate	6	Auto Plate with reagent buffers
Proteinase K	1.0 mL x 1	Proteinase K
Elution Buffer	1.5 mL x 1	Nuclease-Free Water
Strip	12	8-channel strip
Protocol	1	Instruction guide for user

6. Auto Plate Content

Well	Buffer	Volume (µL)
1 / 7	Lysis Buffer	400
2 / 8	Washing Buffer 1	800
3 / 9	Magnetic Beads	800
4 / 10	Washing Buffer 2	800
5 / 11	Washing Buffer 2	800
6 / 12	Elution Buffer	80

7. Kit Storage and Shelf Life

- Components under room temperature (15~35°C) can be stored until the expiration date labeled on the box.
- The proteinase K is transported at room temperature. Upon received, please store proteinase K at 2~8°C.

8. Precautions

- For research use only.
- Avoid using expired reagents.
- When the temperature is below 20°C, place the Auto Plates / Auto Tubes in an oven (preheated 42~60°C) 5 to 10 minutes.
- Avoid vigorous shaking, in order to avoid excessive formation of foam.
- Carefully remove aluminum foil to avoid splashing.
- Do not expose the opened reagents or Auto Plates / Auto Tubes to air. The evaporation would lead to pH change, or effect on the extraction effectiveness.
- Please check the integrity of the Auto Plates / Auto Tubes and remember to insert the strips into the appropriate position of the suitable instrument before operating them.
- Please wear a mask and disposable gloves when handling.
- Use sterile consumables to avoid nuclease contamination.
- Reagent solution contains guanidine salt, avoid using bleach containing detergent.
- Avoid eyes, skin, and clothing contact with reagents. In case of any contact, flush with flowing water.
- If any serious incident occurs, please report to the manufacturer and the competent authority of the member state in which the user and/or the patient is established.

9. Materials required, Not Supplied

- TANBead® Nucleic Acid Extraction System
Model: SLA-16 / 32 / E13200 series (non-sterile)
- DTT (dithiothreitol)
- Disposable gloves
- Scissors, utility knives
- Micropipette, disposable tips (10 µL / 200 µL / 1000 µL)
- 1.5 mL microcentrifuge tube
- 15 mL / 50 mL conical tube

10. Sample Collection, Transportation, and Storage

■ Sample collection and storage

The collection of samples should follow the guidance of collecting container provided by the supplier. And the storage of collected sample should follow the guidance or regulation of local authority.

■ Specimen transportation

The transportation of cervical swab or liquid based cytology samples should be followed by specific pathogen transportation-related regulations.

11. Nucleic Acids Extraction Protocol

Before operating, turn on the warm-up system of TANBead® Nucleic Acid Extractor, if it is equipped with temperature controller, please setting at 70°C.

- Carefully remove the aluminum foil on the Auto Plates.
- Add **300 µL cervical swab** or **liquid based cytology samples** and **10 µL Proteinase K** into well **#1 / #7** of Auto Plate.
Note: For nucleic acids extraction of **mucus samples**, please transfer **300 µL cervical swab** or **liquid based cytology samples** into the 1.5 mL microcentrifuge tube, add **20 µL 1M DTT (dithiothreitol)** and vortex for 10 sec. Briefly spin down the samples and **incubate for 10 - 20 mins at 37°C**. Then transfer **320 µL samples** into well **#1 / #7** of Auto Plate and **10 µL Proteinase K** into well **#1 / #7**.
- Push Auto Plates completely to the bottom of the plate the rack. Make sure that the chamfer of the plate is at the lower left.
- Push strips completely to the bottom of strip rack frame.
- Close the door panel.
- Select the program "**61H**". The parameters are given in following section.
- Carefully remove the Auto Plates when the program is finished.
- Use micropipette to transfer the purified nucleic acids from well **#6 / #12** to a clean tube.
- Discard used Auto Plates and strips into the waste recycling bin.

12. Program

■ SLA-16 / 32 series

Program Name: 61H					Model: SLA-16 / 32 series			
Step	Well	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
1	3	0	30	ON	Medium	800	OFF	0
2	1	20	30	ON	Medium	800	OFF	0
3	2	1	30	ON	Medium	800	OFF	0
4	4	1	30	ON	Medium	800	OFF	0
5	5	1	30	ON	Medium	800	OFF	5
6	6	2	60	ON	Medium	100	OFF	0
7	3	1	0	OFF	Medium	800	OFF	0
8	0	0	0	OFF	Medium	0	OFF	0

■ SLA-E13200 series

Program Name: 61H						Model: SLA-E13200 series			
Step	Well	Temp (°C)	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
1	3	70	0	30	ON	Medium	800	OFF	0
2	1	70	20	30	ON	Medium	800	OFF	0
3	2	70	1	30	ON	Medium	800	OFF	0
4	4	70	1	30	ON	Medium	800	OFF	0
5	5	70	1	30	ON	Medium	800	OFF	5
6	6	70	2	60	ON	Medium	100	OFF	0
7	3	70	0.1	0	OFF	Medium	800	OFF	0
8	0	NA	0	0	OFF	Medium	0	OFF	0

13. Result

Nucleic acid product purified by TANBead® nucleic acid extraction kit can perform qualitative/ quantitative analysis of specific genes by PCR, Q-PCR. Please refer to the molecular diagnostic kit manual.

14. Reagent performance

■ Repeatability

Under repeatability conditions where nucleic acids are extracted with the same reagent kit on the same source samples by the same operator. The coefficient of variation of nucleic acid extraction concentration is less than 5%.














■ Reproducibility

A five-day reproducibility test was carried out with the same source samples for 5 consecutive days with the same reagent kit by different operators. The coefficient of variation of nucleic acid extraction concentration is less than 5%.

■ The stability of extracted DNA

Storage Conditions	DNA stability
-80°C	Over 90 days
-20°C	28 days
4°C	14 days
25°C	2 days
Freeze-thaw	10 times

15. Explanation of Symbols

	Manufacturer		Consult instructions for use
	Temperature limit		Contains sufficient for test
	Catalogue number		Caution
	Batch code		Non-sterile
	Do not re-use		Keep away from sunlight
	Date of manufacture		Use-by date
	For research use only		